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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,421	01/31/2002	Tetsuo Shibuya	YOR920010126US2	6845

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EXAMINER
LY, CHEYNE D

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/059,421	SHIBUYA ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 04, 2004 has been entered.

2. Applicant's arguments, filed October 22, 2004, has been responded to in the instant Office Action.

3. Claims 1-29 are under examination.

CLAIM REJECTIONS - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 16-20, 22, and 23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

RESPONSE TO ARGUMENTS

6. On page 10, Applicant argues that claim 23 is directed to a "programmable storage medium...to perform a method for identifying genes", thus is not directed to a process and therefore, is not covered by the MPEP 2106 (IV)(B)(2)(b). It is noted that the pointed to section of the MPEP is directed to statutory process claims. However, the claimed invention as recited by claim 23 is still directed to non-statutory algorithm type subject matter as discussed below.

7. On pages 10-11, Applicant argues that the MPEP 2106 (IV)(B)(2)(b)(ii) on which the Examiner relies, addresses only "Computer-Related Processes." Claim 16 does not recite the

term "computer." Applicant's argument has been fully considered and found to be unpersuasive because when read as a whole, claims 16-20, and 22 embody computer related processes.

BASIS FOR REJECTION

8. Claims 16-20 and 22 are rejected because said claims are directed to a method comprising steps for manipulating sequence data without any physical alteration step, which is considered to be non-statutory subject matter. "For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory." (MPEP § 2106 (IV)(B)(2) (b), part ii). Similar to the nonstatutory example above, the instant invention comprises algorithmic steps for manipulating sequence data without any physical alteration resulted from said analysis or modeling steps. It is acknowledged that the instant invention comprises algorithmic steps for identifying a putative gene wherein the result could potentially have a practical application. However, a process that merely performs a purely mathematical algorithm is nonstatutory despite the fact that it might inherently have some usefulness (MPEP § 2106 (IV)(B)(2) (b), part ii).

9. Claim 23 recites "A programmable storage medium...to perform a method for identifying genes" is directed to non-statutory algorithm subject matter because said claim is directed a computer readable medium comprising nonfunctional descriptive material. It is noted that limitation of "instructions executable by a digital processing apparatus" has been reasonably construed as nonfunctional descriptive material because said material is not structurally and functionally interrelated to the medium. When nonfunctional descriptive material is recorded on

some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement under 35 U.S.C. 101.

CLAIM REJECTIONS - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-6, 9-11, 13-21, 23, and 27-29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nishikawa et al. (December 2000).

RESPONSE TO ARGUMENT

12. Applicant's argument directed to Rigoutsos et al. (1998) has been found to be persuasive.

13. The citation of the Altschul et al. and Baxevanis et al. references are not used as prior art, but only to expand on the inherent features of the well known in the art program, BLASTX.

14. Nishikawa et al. discloses a method and system for functional annotation of full-length cDNA sequences based on a database similarity search results wherein the input device comprises four SUN workstations (page 13, section 2.1), as in instant claim 1, lines 1 and 3.

15. Nishikawa et al. defines a similarity level for an alignment of cDNA sequence with a known amino acid sequence wherein the BLASTX program and Swiss-prot database are used

(page 15, Section 2.3.1, a). It is well known in the art that the BLASTX program compares a DNA query sequence to the protein database by translating said DNA sequence (Baxevanis et al.). Nishikawa et al. uses the ORF annotation system for motif analysis, which represent patterns, and prediction ORFs, cellular localization, and transmembrane regions which represent the identification of putative genes (page 13, section 2.2), as in instant claim 1, lines 4-5, and claims 16, 23, and 27-29.

16. The use of the BLASTX program and Swiss-prot database as disclosed by Nishikawa et al. (page 15, Section 2.3.1, a) further anticipates limitations of claims 2-4.

17. The disclosure of the Swiss-prot database cited above has been reasonably construed as "a parent database comprising at least one amino acid sequence", as in instant claims 5 and 17.

18. Nishikawa et al. discloses in the motif analysis Prosite and Pfam are used as motif databases (page 13, section 2.2), as in instant claims 6 and 18.

19. The ORF annotation system perform initiation codon analysis for identifying ORFs by using ATGpr (page 13, section 2.2) which represents "a portion of said DNA sequence between a start codon and a stop codon" as in instant claim 9.

20. Nishikawa et al. defines a similarity level for an alignment of cDNA sequence with a known amino acid sequence wherein the BLASTX program and Swiss-prot database are used.

Similarity level is defined as a function of alignment variables, such as identity, E-value, and consensus length of the alignment (page 15, Section 2.3.1, a), which represents "a predetermined number of pattern matches...", as in instant claims 10 and 19.

21. The similarity level is defined as a function of alignment variables, such as E-value cited above has been reasonably construed as a type of "weight". E-value is dominant for distinguishing low similarity but for distinguishing high similarity identity is more adequate because E-values of alignments of which identify are 100% are different from each other if the alignments lengths are different (page 15, Section 2.3.1, a), as in instant claims 11 and 20.

22. It is noted that the instant specification does not specifically define any "pattern matching algorithm", therefore, the citation of BLASTX from Altschul et al. (page 15, Section 2.3.1, a, and page 23, Reference number 12), which is a type of dynamic programming algorithm for sequence searching, anticipates instant claim 13.

23. Nishikawa et al. discloses a method of functional annotation for full-length cDNA sequences based on a database similarity search results wherein the input device comprises four SUN workstations and a display system (page 13, section 2.1), as in instant claims 14 and 15.

24. Figure 3 (page 15) illustrates a display for similarity search results as directed to motifs and ORFs, as in instant claim 21.

CLAIM REJECTIONS - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

27. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa et al. (December 2000) taken with Rigoutsos et al. (1998).

28. Nishikawa et al. describes the limitations to claims 1-6, 9-11, 13-21, 23, and 27-29 as discussed above.

29. However, Nishikawa et al. does not describes the limitation of a pattern discovery algorithm such as the TEIRESIAS algorithm required in claims 7, 8, 12, 22, and 24-26.

30. Rigoutsos et al. describe a new algorithm, TEIRESIAS, for the discovery of rigid patterns (motifs) in biological sequences (Abstract etc.), as instant claims 7, 8, 22, and 25.

31. Rigoutsos et al. a pattern-discovery algorithm which uses the SwissProt database comprising amino acid sequences translated from nucleic acid sequences for determining matches by generating a scoring matrix from the pattern of amino acid position of the patterns wherein threshold values are assigned a weight of one for match and nothing for the others. The final score assigned to a sequence is the maximum among all the scores of its offsets, which represents "the sum of weights". The patterns with the highest scoring sequences (exceeds predetermined threshold) determine the sequence of the specific sequence (pages 57, column 1, The algorithm §, to page 59, column 1, and page 60, column 2, Verifying Observations §), as in instant claims 12, 24, and 26.

32. Rigoutsos et al. describes that alignment algorithms such as the alignment algorithm described by Nishikawa et al. suffer from several inherent drawbacks. TEIRESIAS is an improvement for overcoming the difficulty that alignment algorithms have in identifying local similarities (page 55, column 1, Introduction Section, to column 2).

33. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement described by Rigoutsos et al. to utilize TEIRESIAS in the method and system of Nishikawa et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use TEIRESIAS for functional annotation

of full-length cDNA sequences based on a database similarity search results as taught by Nishikawa et al. and Rigoutsos et al.

34. It is noted that the Rigoutsos et al. reference has been previously cited, therefore, said reference has not been provided in the instant Office Action.

CONCLUSION

35. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

36. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

37. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

39. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571)272-0718.

C. Dune Ly
2/28/05

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